DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

d16006

DEC - 6 1996

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

VIA FEDERAL EXPRESS

WARNING LETTER

Mr. Xu Zhi Yong, Factory Director
Shanghai Da Hu Medical Equipment Factory
918 Shi Jin Road
Shanghai, China

Dear Mr. Yong:

During an inspection of your firm located in Shanghai, China, on August 1-2, 1996, our Investigator determined that your firm manufactures ultrasonic therapy devices. The Ultrasonic Therapy Instrument Model CSL-1 is a device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, in that methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to review, evaluate, and maintain by a formally designated unit all records of written and oral complaints relative to the identity, quality, reliability, safety, effectiveness, or performance of a device, as required by 21 CFR 820.198(a). For example, there is no complaint handling program.

2. Failure to perform planned and periodic audits in accordance with written procedures by appropriately trained individuals not having direct responsibility for the matters being audited, as required by 21 CFR 820.20(b). For example, there is no internal quality audit system, and consequently your firm has never been audited.

3. Failure to adequately calibrate all production and quality assurance measurement equipment, as required by 21 CFR 820.61. For example, the following equipment has never been checked or calibrated:

   a.) an electro surgical analyzer, model 453A, S/N 2149, calibration was due 5/16/94;

b.) spectrum analyzer, model M562B3, S/N W0812005, calibration was due 7/20/95;

c.) Rode & Schwartz Signal Generator, model SMS, S/N 8721651014, calibration was due 12/7/93; and,

d.) National Oscilloscope UP-5234A, calibration was due 5/12/95.

We also noted that this device is subject to a radiation performance standard, specifically 21 CFR 1050.10, and is required to adhere to that standard. A follow-up packet of information pertaining to that performance standard will be mailed to your attention.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions will be cleared until the violations have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. All correspondence must be submitted with an English translation.

Your response should be sent to Ms. Brenda Hayden, Interdisciplinary Scientist, Food and Drug Administration, 2098 Gaither Road, HFZ-343, Rockville, Maryland 20850.

For questions concerning the radiation performance standard, please contact Ms. Joanne Barron at (301) 594-4654.

Sincerely yours,

Lillian Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

cc: Mrs. Lu Rao
CAI Industries
800 S. Palm Avenue
Suite 10
Alhambra, California